



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 28 2009

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Transenterix, Inc.  
% Ms. Tammy Carrea  
Director, Regulatory Affairs  
and Quality Assurance  
3908 Patriot Drive, Suite 170  
Durham, North Carolina 27703

Re: K091697

Trade/Device Name: SPIDER™ (Single Port Instrument Delivery Extended Reach)  
Surgical Instruments

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: Class II

Product Code: GCJ

Dated: August 19, 2009

Received: August 20, 2009

Dear Ms. Carrea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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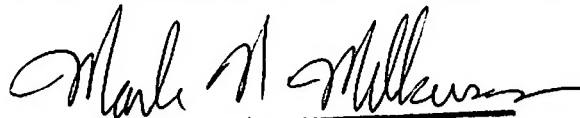
510(k) No.	K091697	
If known		

### Indications For Use Statement

Device Name: **SPIDER™ (Single Port Instrument Delivery Extended Reach)  
Surgical Instruments**

**Indications For Use:**

The SPIDER™ Surgical Instruments are intended for use in minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating, suction/irrigation and other manipulation of tissues and vessels during laparoscopic procedures.



(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K091697

Prescription Use ☒             
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)